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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,892	09/30/2003	Michael John Reed	674519-2011.1	4836

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,892

Applicant(s)

REED ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-32 and 65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-32 and 65 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/2004 & 8/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

Non-Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

2. The disclosure is objected to because of the following informalities:

It contains (a) two sets of brief description of drawings and (b) refers to two each of figures 1-12 (see pages 14 and 52 of the present specification).

Appropriate correction is required.

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.

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- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

4. The rejection of claim 66 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is made moot by the cancellation of the instant claim.

5. Claim 65 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating breast cancer, does not reasonably provide enablement for inhibiting. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are

taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claim recites "inhibiting and/or treating breast cancer". The term "inhibit" is inclusive of "preventing" and, thus, the claim is read to encompass the prevention of breast cancer. The disclosed compound(s) have been shown to inhibit the activity of steroid sulphatase and, thus, to be useful as a therapeutic agent. However, the claim encompasses using the compound to prevent breast cancer which is clearly beyond the scope of the instantly claimed/disclosed invention. Please note that the term 'prevent' is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treat," especially since it is well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies. Therefore, in order to practice the claimed invention commensurate in scope with the claimed invention, the skilled artisan would have to determine the ability of the claimed compounds to prevent/inhibit breast cancer in vivo which would require a determination of a person prone to said disease and, thus, in need of preventive therapy.

6. The rejection of claim 66 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claim.

7. The rejection of claims 7 and 21 under 35 USC 112, second paragraph is withdrawn.

Duplicate Claims

8. The objection to claim 4 under 37 CFR 1.75 as being a substantial duplicate of claim 1 is made moot by the cancellation of the instant claim.

Double Patenting

9. The rejections of claims 4 and 66 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 5, 830,886 and 6,903,084 and US Application Nos. 10/367,114 and 10/955,962 as well of patents and applications listed in paragraph 15 of the previous Office Action are made moot by the cancellation of the instant claims.

10. The rejections of claims 1-3, 5-7, 9-32 and 65 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 5, 830,886 and 6,903,084 and US Application Nos. 10/367,114 and 10/955,962 as well of patents and applications listed in paragraph 15 of the previous Office Action are maintained.

Applicant argues that in order for an obviousness-type double patenting rejection to stand, it must be shown that the claims in this application are obvious "based solely on the claims in the prior patent; the disclosure in the prior patent cannot be used as prior art". The same argument applies to the copending Applications. Applicant's argument was considered but not persuasive for the following reason.

The examiner agrees that obviousness-type double patenting is based on the claimed invention of the cited reference and the instant claims. The examiner also

agrees that the disclosure of the cited reference cannot be used as prior art. However, those portions of the specification, which provide support for the patent claims, can be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention in the cited reference (see MPEP § 804, B(1)). The utilization of the disclosure of the cited references in this case is not as prior art but to support and define the claimed inventions of said references as allowed by the MPEP. It is also noted that some of the claims of the cited reference recite 2-substituted steroid nucleus (see for example claim 1 of US 6,903,084; claim 2 of US 6,476,011, etc.).

For this reason and those given in the previous Office Action, the rejections of claims 1-3, 5-7, 9-32 and 65 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 5, 830,886 and 6,903,084 and US Application Nos. 10/367,114 and 10/955,962 as well of patents and application listed in paragraph 15 of the previous Office Action are maintained.

Claim Rejections - 35 USC § 103

11. The rejection of claims 4 and 66 under 35 USC 103(a) over Reed et al. (WO 93/05064) is made moot by the cancellation of the instant claims.

12. The rejection of claims 1-3, 5-7, 9-32 and 65 under 35 USC 103(a) over Reed et al. (WO 93/05064) is withdrawn.


13. The rejection of claims 2, 3, 9, 10 and 32 under 35 USC 103(a) over Prezewowsky et al. (US 3,951,959) is withdrawn.

Telephone Inquiry

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
October 19, 2006